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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

February 21, 1978

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LEGISLATIVE REFERRAL MEMORANDUM

78-0598

TO: Legislative Liaison Officer
Central Intelligence Agency

SUBJECT: HEW views on the proposed report of the CIA concerning S. 1893, a bill "To amend the Public Health Service Act to establish the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and for other purposes."

The Office of Management and Budget requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

A response to this request for your views is needed no later than March 3, 1978.

Questions should be referred to John Lively (395-4794) or to Jim Stimpson (395-3736), the legislative analyst in this office.

Naomi R. Sweeney

Naomi R. Sweeney, for
Assistant Director for
Legislative Reference

Enclosures



FEB 2 1973

The Honorable James T. McIntyre, Jr.
Acting Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. McIntyre:

This is in response to your request for our views on the proposed report of the Central Intelligence Agency (CIA) concerning S. 1893, a bill "To amend the Public Health Service Act to establish the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and for other purposes".

In summary, we object to the submission of the CIA's report to the Senate Human Resources Committee because the bill, with the CIA's recommended amendments, would seriously compromise the current policy and practice of the Department of Health, Education, and Welfare in protecting human subjects of biomedical and behavioral research, and because it is neither feasible nor desirable to authorize members of Human Investigation Review Boards to review classified information.

S. 1893 would create a permanent Commission composed of eleven members appointed by the President, plus nonvoting ex officio advisors from the Department of Health, Education, and Welfare; the Department of Defense; the Veterans' Administration; the National Science Foundation; the Office of Science and Technology Policy; and the Central Intelligence Agency. The Commission would be required to undertake a study to identify the basic ethical principles which underlie research involving human subjects, develop guidelines to implement these principles, and advise and monitor Federal agencies as the guidelines are implemented. The Commission would also be required to identify basic ethical principles underlying the delivery of health services and oversee their transfer into guidelines. The Commission would determine requirements for informed consent for children, prisoners, military personnel, and the institutionalized mentally infirm involved as subjects of research. The Commission would also be required to study

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the nature and scope of injuries suffered by research subjects, develop guidelines for Human Investigation Review Boards (which would replace Institutional Review Boards) in institutions receiving federal support, and study the ethical, legal, and social implications of advances in biomedical and behavioral research. An individual would be required to receive, prior to his appointment as a member of the Commission, all security clearances necessary to assure access to information which is properly classified for any purpose by a federal agency.

The CIA's proposed report maintains that there is no conflict between the existing CIA policy and the aims of S. 1893. It recommends that the bill be amended to (1) forbid disclosure by the Commission of all information "requiring protection in the interests of national security", (2) require experts, consultants, or contractors hired by the Commission to be subject to the same security requirements as the Commission, and (3) prohibit Human Investigation Review Boards from disclosing confidential information.

S. 1893, if enacted into law with the CIA's proposed amendments, would seriously compromise the current policy and practice of the Department of Health, Education, and Welfare. That policy requires that all research applications received by the Department be made available to any member of the public on request at the time that the research is funded. Furthermore, it is customary for Institutional Review Boards (which under S. 1893 would become Human Investigation Review Boards) to hold their meetings in open forum. Unless the amendments proposed in the CIA report would pertain solely to that agency, the amendments could undermine the credibility of this Department's research review system, which relies on public access as an assurance that the rights and well-being of human subjects are not jeopardized in the name of research.

Furthermore, the proposed CIA report assumes that members of Human Investigation Review Boards could be prohibited from disclosing confidential information (presumably concerning national security). Since members of such Boards are nonfederal volunteers, it is not feasible to permit them to review information concerning national security and to require them to treat it in a confidential manner.

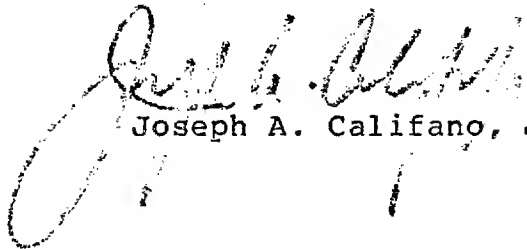
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The diversity of research problems experienced by different agencies, as evidenced by constraints necessary to the conduct of CIA research, but inimical to HEW procedures, constitutes a serious obstacle to the design of effective government-wide ethics advisory bodies. This Department is currently considering alternative approaches to assuring the uniformity of federal research safeguards which take account of the unique needs of each agency. For this reason we oppose submission of the CIA report and do not intend to submit a bill report on this legislation at this time.

We therefore object to the submission of the CIA's report to the Committee.

Sincerely,



Joseph A. Califano, Jr.